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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEVADA**

BAYER SCHERING PHARMA AG &  
BAYER HEALTHCARE  
PHARMACEUTICALS, INC.,  
Plaintiffs,

vs.

MYLAN PHARMACEUTICALS INC.,  
MYLAN INC., AND FAMY CARE LTD,  
Defendants.

Case No. : 2:11-cv-00604-KJD-LRL

**ANSWER, DEFENSES AND  
COUNTERCLAIMS OF MYLAN  
PHARMACEUTICALS INC., MYLAN  
INC. AND FAMY CARE LTD.**

Defendants Mylan Pharmaceuticals Inc. (“Mylan Pharmaceuticals”), Mylan Inc. (collectively “Mylan”), and Famy Care Ltd. (“Famy Care”; Mylan and Famy Care collectively “Defendants”) answer the Complaint of Plaintiffs Bayer Schering Pharma AG (“Bayer Schering”) and Bayer HealthCare Pharmaceuticals Inc. (“Bayer HealthCare”; collectively “Bayer”) as follows:

**PARTIES**

1. Plaintiff Bayer Schering Pharma AG (“Bayer Schering”), formerly known as Schering AG, is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business in Müllerstrasse 178, 13353 Berlin, Germany.

**ANSWER:** Upon information and belief, Defendants admit that Bayer Schering has a place of business in Müllerstrasse 178, 13353 Berlin, Germany. Defendants lack sufficient knowledge and information to form a belief as to the truth of the remaining allegations in paragraph 1, and, on that basis, Defendants deny those allegations.

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2. Plaintiff Bayer HealthCare Pharmaceuticals Inc. (“Bayer HealthCare”), formerly known as Berlex, Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6 West Belt, Wayne, New Jersey 07470.

**ANSWER:** Defendants lack sufficient knowledge and information to form a belief as to the truth of the allegations in paragraph 2, and, on that basis, Defendants deny those allegations.

3. On information and belief, Defendant Mylan Pharmaceuticals Inc. (“MPI”) is a corporation organized under the laws of West Virginia, having a principal place of business at 781 Chestnut Ridge Rd., Morgantown, West Virginia 26505. MPI is registered to do business in the State of Nevada and has identified CSC Services of Nevada, Inc., 2215-B Renaissance Dr., Las Vegas, NV 89119, as its registered agent for service of process.

**ANSWER:** Mylan Pharmaceuticals admits that it is a corporation organized under the laws of West Virginia with a place of business at 781 Chestnut Ridge Rd., Morgantown, West Virginia 26505. Mylan Pharmaceuticals avers that, as of the date of the filing of this Answer, it is registered with the Nevada Department of State as a foreign profit corporation and that the registration documents speak for themselves and are the best evidence of their contents. Mylan Pharmaceuticals avers that CSC Services of Nevada, Inc., 2215-B Renaissance Dr., Las Vegas, NV 89119 is Mylan Pharmaceuticals’s registered agent in Nevada. Defendants deny the remaining allegations in paragraph 3.

4. On information and belief, Defendant Mylan Inc. is a corporation organized under the laws of Pennsylvania, having a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

**ANSWER:** Mylan Inc. admits that it is a corporation organized under the laws of Pennsylvania. Mylan Inc. has a place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Defendants deny the remaining allegations in paragraph 4.

5. On information and belief, Defendant Famy Care Ltd. (“Famy Care”) is a corporation organized under the laws of India, having a principal place of business at 3rd Floor, Brady House, 12/14, Veer Nariman Road, Fort, Mumbai - 400 001, India.

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1           **ANSWER:** Famy Care admits that it is a corporation organized under the laws of  
2 India with a place of business at 3rd Floor, Brady House, 12/14, Veer Nariman Road, Fort,  
3 Mumbai - 400 001, India. Defendants deny the remaining allegations in paragraph 5.

4           6. On information and belief, on or about August 6, 2008, Famy Care entered into a  
5 partnership with Mylan Inc. pursuant to which the two companies would develop and supply  
6 generic oral contraceptives to customers in the United States.

7           **ANSWER:** Denied.

8           7. On information and belief, Famy Care is in the business of, among other things,  
9 manufacturing and marketing generic pharmaceutical products, including oral contraceptives.

10           **ANSWER:** Famy Care admits that it manufactures and sells generic pharmaceutical  
11 products, including oral contraceptives. Defendants deny the remaining allegations in paragraph

12           8. On information and belief, Mylan Inc. is in the business of, among other things,  
13 manufacturing and selling generic copies of branded pharmaceutical products through various  
14 operating subsidiaries and partners, including MPI and Famy Care.

15           **ANSWER:** Denied.

16           9. On information and belief, MPI is in the business of, among other things, manufacturing  
17 and selling generic copies of branded pharmaceutical products throughout the United States  
18 including within the State of Nevada.

19           **ANSWER:** Mylan Pharmaceuticals admits that it manufactures and sells generic  
20 pharmaceutical products. Defendants deny the remaining allegations in paragraph 9.

21           10. On information and belief, MPI is a wholly-owned subsidiary of Mylan Inc.

22           **ANSWER:** Mylan admits that Mylan Pharmaceuticals is a wholly-owned subsidiary  
23 of Mylan Inc.

24           11. On information and belief, MPI and Mylan Inc. have common officers and directors.

25           **ANSWER:** Denied.

26           12. On information and belief, MPI is an alter ego of Mylan Inc.

27           **ANSWER:** Denied.

28           13. On information and belief, MPI is the U.S. agent for Famy Care with regard to numerous

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1 Abbreviated New Drug Application (“ANDAs”) held by Famy Care and on file with the U.S.  
2 Food and Drug Administration (“FDA”), including without limitation ANDA No. 20-2594.

3 **ANSWER:** Mylan Pharmaceuticals admits that it is the U.S. agent for Famy Care with  
4 regard to ANDA No. 20-2594. Defendants deny the remaining allegations in paragraph 13.

5 14. On information and belief, MPI, Mylan Inc., and Famy Care have entered into an  
6 agreement whereby MPI will distribute in the United States, including Nevada, at least the  
7 product for which approval is sought by ANDA No. 20-2594, if such ANDA is approved by the  
8 FDA.

9 **ANSWER:** Mylan Pharmaceuticals and Famy Care admit that they have entered into  
10 an agreement whereby Mylan Pharmaceuticals has a right to distribute the product for which  
11 approval is sought by ANDA No. 20-2594, if such ANDA is approved by the FDA. Defendants  
12 deny the remaining allegations of paragraph 14.

13 15. On information and belief, MPI and Mylan Inc. are the alter egos of Famy Care,  
14 including without limitation for the purposes of ANDA No. 20-2594.

15 **ANSWER:** Denied.

16 16. On information and belief and consistent with their stated intentions, following any FDA  
17 approval of an ANDA 20-2594, MPI, Mylan Inc., and Famy Care will act in concert to  
18 distribute and sell any generic product approved as a result of ANDA 20-2594 throughout the  
19 United States, including within Nevada. On information and belief, MPI, Mylan Inc., and Mylan  
20 Pharmaceuticals Inc. know and intend that any generic product approved as a result ANDA No.  
21 20-2594 will be distributed and sold in the United States, including within Nevada.

22 **ANSWER:** Denied.

23 17. On information and belief, MPI, Mylan Inc., and Famy Care acted in concert to prepare  
24 and submit ANDA No. 20-2594.

25 **ANSWER:** Denied.

26 18. On information and belief, MPI, Mylan Inc., and Famy Care actively participated in the  
27 preparation of ANDA No. 20-2594, and these entities caused submission of this ANDA to the  
28 FDA.

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1           **ANSWER:** Denied.

2                                   **JURISDICTION AND VENUE**

3       19.     This action arises under the patent laws of the United States of America. This Court has  
4 jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

5           **ANSWER:** Defendants admit that the Court has subject matter jurisdiction over the  
6 claims in this action, but deny that Mylan Inc. is a proper party to this action.

7       20.     On information and belief, Mylan Inc. is subject to personal jurisdiction in the State of  
8 Nevada because, among other things, Mylan Inc. (itself and through its wholly-owned operating  
9 subsidiary MPI) has purposely availed itself of the benefits and protections of Nevada's laws  
10 such that it should reasonably anticipate being haled into court here.

11           **ANSWER:** Defendants do not contest personal jurisdiction for the purpose of this  
12 action only. Defendants deny that Mylan Inc. is a proper party to this action and deny the  
13 remaining allegations of paragraph 20.

14       21.     On information and belief, Mylan Inc. (itself and through its wholly-owned operating  
15 subsidiary MPI) markets and sells generic drugs throughout the United States and in particular  
16 within the State of Nevada, and therefore Mylan Inc. transacts business within the State of  
17 Nevada such that it has engaged in systematic and continuous business contacts within the State  
18 of Nevada. In addition, Mylan Inc. is subject to personal jurisdiction in Nevada because, on  
19 information and belief, it controls and dominates MPI and therefore the activities of MPI in this  
20 jurisdiction are attributed to Mylan Inc.

21           **ANSWER:** Defendants do not contest personal jurisdiction for the purpose of this  
22 action only. Defendants deny the remaining allegations of paragraph 21.

23       22.     On information and belief, Mylan Inc. (itself or through its subsidiary MPI) markets its  
24 generic drug products to residents of the State of Nevada through its website.

25           **ANSWER:** Denied.

26       23.     On information and belief, Mylan Inc. (itself or through its subsidiary MPI) offers its  
27 generic drug products for sale to residents of the State of Nevada on third-party websites that  
28 Nevada residents can use to purchase Mylan Inc.'s products for shipment to and within the State

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1 of Nevada.

2 **ANSWER:** Denied.

3 24. On information and belief, residents of the State of Nevada purchase generic drug  
4 products from Mylan Inc. (itself or through its subsidiary MPI) in the State of Nevada.

5 **ANSWER:** Denied.

6 25. On information and belief, Mylan Inc. (itself or through its subsidiary MPI) receives  
7 revenue from the sales and marketing of its generic drug products in the State of Nevada.

8 **ANSWER:** Denied.

9 26. On information and belief, Mylan Inc. (itself or through its subsidiary MPI) uses sales  
10 representatives in the State of Nevada to promote the sales of Mylan Inc.'s generic drugs  
11 throughout the State of Nevada.

12 **ANSWER:** Denied.

13 27. On information and belief, Mylan Inc. (itself or through its subsidiary MPI) has attended  
14 trade shows in the State of Nevada for the purpose of promoting and selling Mylan Inc.'s generic  
15 drug products.

16 **ANSWER:** Denied.

17 28. On information and belief, Mylan Inc. (itself or through its subsidiary MPI) has several  
18 authorized distributors in the State of Nevada to distribute Mylan Inc.'s generic drug products  
19 throughout the State of Nevada.

20 **ANSWER:** Denied.

21 29. On information and belief, Mylan Inc. (itself or through its subsidiary MPI) plans to  
22 market and sell the product that is the subject of ANDA No. 20-2594, if approved, in the State of  
23 Nevada as an alternative to Bayer's YAZ® product currently being sold in the State of Nevada.

24 **ANSWER:** Denied.

25 30. On information and belief, MPI is subject to personal jurisdiction in the State of Nevada  
26 because, among other things, MPI, itself and through its parent Mylan Inc., has purposely availed  
27 itself of the benefits and protections of Nevada's laws such that it should reasonably anticipate  
28 being haled into court here.

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1           **ANSWER:** Defendants do not contest personal jurisdiction in this district for the  
2 purposes of this action only. Defendants deny the remaining allegations in paragraph 30.

3 31. MPI has purposely availed itself of the benefits and protections of Nevada's laws by  
4 registering with the State of Nevada to do business in Nevada and by maintaining an agent for  
5 service of process in Nevada. By maintaining an agent for service of process in Nevada, MPI has  
6 reasonably anticipated being haled into court here.

7           **ANSWER:** Denied.

8 32. On information and belief, MPI, itself and through its parent Mylan Inc., markets and  
9 sells generic drugs throughout the United States and in particular within the State of Nevada, and  
10 therefore MPI transacts business within the State of Nevada such that it has engaged in  
11 systematic and continuous business contacts within the State of Nevada.

12           **ANSWER:** Mylan Pharmaceuticals admits that it sells generic drugs. Defendants deny  
13 the remaining allegations in paragraph 32.

14 33. On information and belief, MPI (itself or through its parent Mylan Inc.) markets its  
15 generic drug products to residents of the State of Nevada through its website.

16           **ANSWER:** Denied.

17 34. On information and belief, MPI (itself or through its parent Mylan Inc.) offers its generic  
18 drug products for sale to residents of the State of Nevada on third-party websites that Nevada  
19 residents can use to purchase MPI's products for shipment to and within the State of Nevada.

20           **ANSWER:** Denied.

21 35. On information and belief, residents of the State of Nevada purchase generic drug  
22 products from MPI (itself or through its parent Mylan Inc.) in the State of Nevada.

23           **ANSWER:** Denied.

24 36. On information and belief, MPI (itself or through its parent Mylan Inc.) receives revenue  
25 from the sales and marketing of its generic drug products in the State of Nevada.

26           **ANSWER:** Denied.

27 37. On information and belief, MPI (itself or through its parent Mylan Inc.) uses sales  
28 representatives in the State of Nevada to promote the sales of MPI's generic drugs throughout



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1 the State of Nevada.

2 **ANSWER:** Denied.

3 38. On information and belief, MPI (itself or through its parent Mylan Inc.) has attended  
4 trade shows in the State of Nevada for the purpose of promoting and selling MPI's generic drug  
5 products.

6 **ANSWER:** Denied.

7 39. On information and belief, MPI (itself or through its parent Mylan, Inc.) has several  
8 authorized distributors in the State of Nevada to distribute MPI's generic drug products  
9 throughout the State of Nevada.

10 **ANSWER:** Denied.

11 40. On information and belief, MPI (itself or through its parent Mylan, Inc.) plans to market  
12 and sell the product that is the subject of ANDA No. 20-2594, if approved, in the State of  
13 Nevada as an alternative to Bayer's YAZ® product currently being sold in the State of Nevada.

14 **ANSWER:** Denied.

15 41. On information and belief, Famy Care is subject to personal jurisdiction in the State of  
16 Nevada because, among other things, Famy Care, itself and through its agent MPI and its partner  
17 Mylan Inc., has purposely availed itself of the benefits and protections of Nevada's laws such  
18 that it should reasonably anticipate being haled into court here.

19 **ANSWER:** Defendants do not contest personal jurisdiction in this district for the  
20 purposes of this action only. Defendants deny the remaining allegations in paragraph 41.

21 42. Fanny Care has purposely availed itself of the benefits and protections of Nevada's laws  
22 by designating MPI as its U.S. agent for numerous ANDA applications (including ANDA 20-  
23 3594). MPI has registered with the State of Nevada to do business in Nevada and maintains an  
24 agent for service of process in Nevada. By designating an agent that maintains an agent for  
25 service of process in Nevada, Famy Care has reasonably anticipated being haled into court here.

26 **ANSWER:** Famy Care admits that it has designated Mylan Pharmaceuticals as its U.S.  
27 agent for ANDA 20-3594. Defendants deny the remaining allegations in paragraph 42.

28 43. On information and belief, Famy Care, itself and through its agent MPI and its partner



1 Mylan Inc., markets and sells generic drugs throughout the United States and in particular within  
2 the State of Nevada, and therefore Famy Care transacts business within the State of Nevada such  
3 that it has engaged in systematic and continuous business contacts within the State of Nevada.

4 **ANSWER:** Denied.

5 44. On information and belief, Famy Care (itself or through its agent MPI and its partner  
6 Mylan Inc.) markets its generic drug products to residents of the State of Nevada through its  
7 website.

8 **ANSWER:** Denied.

9 45. On information and belief, Famy Care (itself or through its agent MPI and its partner  
10 Mylan Inc.) offers its generic drug products for sale to residents of the State of Nevada on third-  
11 party websites that Nevada residents can use to purchase Famy Care's products for shipment to  
12 and within the State of Nevada.

13 **ANSWER:** Denied.

14 46. On information and belief, residents of the State of Nevada purchase generic drug  
15 products from Famy Care (itself or through its agent MPI and its partner Mylan Inc.) in the State  
16 of Nevada.

17 **ANSWER:** Denied.

18 47. On information and belief, Famy Care (itself or through its agent MPI and its partner  
19 Mylan Inc.) receives revenue from the sales and marketing of its generic drug products in the  
20 State of Nevada.

21 **ANSWER:** Denied.

22 48. On information and belief, Famy Care (itself or through its agent MPI and its partner  
23 Mylan Inc.) uses sales representatives in the State of Nevada to promote the sales of Famy  
24 Care's generic drugs throughout the State of Nevada.

25 **ANSWER:** Denied.

26 49. On information and belief, Famy Care (itself or through its agent MPI and its partner  
27 Mylan Inc.) has attended trade shows in the State of Nevada for the purpose of promoting and  
28 selling Famy Care's generic drug products.

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1           **ANSWER:** Denied.

2       50. On information and belief, Famy Care (itself or through its agent MPI and its partner  
3 Mylan Inc.) has several authorized distributors in the State of Nevada to distribute Famy Care's  
4 generic drug products throughout the State of Nevada.

5           **ANSWER:** Denied.

6       51. On information and belief, Famy Care (itself or through its agent MPI and its partner  
7 Mylan Inc.) plans to market and sell the product that is the subject of ANDA No. 20-2594, if  
8 approved, in the State of Nevada as an alternative to Bayer's YAZ® product currently being sold  
9 in the State of Nevada.

10          **ANSWER:** Denied.

11       52. Venue is proper under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

12          **ANSWER:** Defendants do not contest venue in this judicial district, but specifically  
13 deny that this judicial district is the most appropriate and convenient venue for this action.

14                                   **BACKGROUND**

15       53. Bayer HealthCare is the holder of approved New Drug Application ("NDA") No. 21-676  
16 for YAZ® tablets, which contain as active ingredients micronized drospirenone and micronized  
17 17 $\alpha$ -ethinylestradiol. The United States Food and Drug Administration ("FDA") has approved  
18 YAZ® tablets for the prevention of pregnancy in women and for the treatment of moderate acne  
19 and the symptoms of premenstrual dysphoric disorder in women who elect to use an oral  
20 contraceptive.

21          **ANSWER:** Defendants admit that Bayer HealthCare is indicated in the records of the  
22 FDA as the holder of New Drug Application ("NDA") No. 21-676 for Yaz® brand tablets.  
23 Defendants lack sufficient knowledge and information to form a belief as to the truth of the  
24 remaining allegations in paragraph 53 and, on that basis, Defendants deny those allegations.

25       54. Bayer HealthCare sells YAZ® tablets in the United States as a 28-day oral contraceptive  
26 regimen that contains 24 tablets comprising 3 mg of micronized drospirenone and 0.02 mg of  
27 micronized 17 $\alpha$ -ethinylestradiol plus 4 placebo tablets.

28          **ANSWER:** Upon information and belief, Defendants admit that Bayer HealthCare

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1 sells YAZ® tablets in the United States as a 28-day oral contraceptive regimen that contains 24  
2 tablets comprising 3 mg of drospirenone and 0.02 mg of 17 $\alpha$ -ethinylestradiol. Defendants lack  
3 sufficient knowledge and information to form a belief as to the truth of the remaining allegations  
4 in paragraph 54, and, on that basis, Defendants deny those allegations.

5 55. On information and belief, Mylan submitted to the FDA ANDA No. 20-2594 (“Mylan’s  
6 ANDA”) under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the  
7 commercial manufacture, use, offer for sale, sale and/or importation of a generic version of  
8 Bayer’s YAZ® tablets.

9 **ANSWER:** Defendants aver that ANDA No. 20-2594 speaks for itself and is the best  
10 evidence of its contents. Defendants deny the remaining allegations in paragraph 55.

11 56. On information and belief, the composition of the product that is the subject of Mylan’s  
12 ANDA contains 3 mg of drospirenone and 0.02 mg of ethinylestradiol in tablet form for oral  
13 contraception in a human female (hereinafter “Mylan’s YAZ® ANDA product”).

14 **ANSWER:** Defendants aver that ANDA No. 20-2594 speaks for itself and is the best  
15 evidence of its contents. Defendants deny the remaining allegations in paragraph 56.

16 57. On information and belief, Mylan’s ANDA seeks approval of a 28-day oral contraceptive  
17 regimen that contains 24 tablets comprising 3 mg of drospirenone and 0.02 mg 17  $\alpha$ -  
18 ethinylestradiol plus 4 placebo tablets.

19 **ANSWER:** Defendants aver that ANDA No. 20-2594 speaks for itself and is the best  
20 evidence of its contents.

21 58. On information and belief, on or about March 7, 2011, Mylan sent a Notice Letter to  
22 Plaintiffs Bayer Schering and Bayer HealthCare, purporting to comply with the provisions of 21  
23 U.S.C. § 355(j)(2)(B) and the FDA regulations relating thereto.

24 **ANSWER:** Defendants admit that McGuireWoods LLP sent a Notice Letter dated  
25 March 7, 2011, on behalf of Mylan Pharmaceuticals and Famy Care, to Bayer Schering and  
26 Bayer HealthCare in compliance with the provisions of 21 U.S.C. § 355(j)(2)(B) and the FDA  
27 regulations relating thereto.

28 ///

**PATENT-IN-SUIT**

59. The patent-in-suit is United States Reissue Patent No. 37,564 (“the ’564 reissue patent”).

**ANSWER:** On information and belief, Defendants aver that one of the patents-in-suit is United States Reissue Patent No. 37,564 (“the ’564 reissue patent”).

60. The ’564 reissue patent issued on February 26, 2002. Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their application for this patent on February 15, 2000. Bayer Schering is the current owner of the ’564 reissue patent. Bayer attaches a true and correct copy of the ’564 reissue patent as Exhibit 1.

**ANSWER:** Defendants admit that, according to the electronic records of the United States Patent and Trademark Office (“PTO”), the PTO issued the ’564 reissue patent on or about February 26, 2002. Defendants admit that Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke are named on the face of the patent as the inventors of the ’564 reissue patent, and that the ’564 reissue patent purports to have been filed on February 15, 2000. Defendants aver that the records of the PTO identify Bayer Schering as the current owner of the ’564 reissue patent. Defendants admit that Bayer purports to have attached a copy of the ’564 reissue patent as Exhibit 1 to the complaint. Defendants lack sufficient knowledge and information to form a belief as to the truth of the remaining allegations in paragraph 60, and, on that basis, Defendants deny those allegations.

**COUNT ONE: CLAIM FOR PATENT INFRINGEMENT OF THE ’564 REISSUE PATENT**

61. Bayer incorporates paragraphs 1-60 of this Complaint as if fully set forth herein.

**ANSWER:** Defendants reassert and incorporate by reference their responses to paragraphs 1-60 above as if fully set forth herein.

62. On information and belief, Mylan’s YAZ® ANDA product infringes one or more claims of the ’564 reissue patent.

**ANSWER:** Denied.

63. The ’564 reissue patent covers Bayer HealthCare’s YAZ® tablets, and Bayer has listed the ’564 reissue patent for YAZ® in the *FDA Approved Drug Products and Therapeutic Equivalence Evaluations* (“the Orange Book”).

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1           **ANSWER:** On information and belief, Defendants admit that the electronic version of  
2 the FDA *Approved Drug Products and Therapeutic Equivalence Evaluations* (“the Orange  
3 Book”) lists the ‘564 reissue patent in connection with YAZ®. Defendants deny the remaining  
4 allegations in paragraph 63.

5 64. On information and belief, Mylan submitted ANDA No. 20-2594 to the FDA for the  
6 purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale  
7 and/or importation of Mylan’s YAZ® ANDA product before the expiration of the ‘564 reissue  
8 patent.

9           **ANSWER:** Defendants admit that ANDA No. 20-2594 was submitted to the FDA.  
10 Defendants deny the remaining allegations in paragraph 64.

11 65. On information and belief, Mylan made and included in ANDA No. 20-2594 a  
12 certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the ‘564  
13 reissue patent is invalid or will not be infringed by the manufacture, use, offer for sale, sale  
14 and/or importation of Mylan’s YAZ® ANDA product.

15           **ANSWER:** Defendants admit that ANDA No. 20-2594 contains a certification under  
16 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ‘564 reissue patent is invalid, unenforceable,  
17 and/or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of the  
18 proposed ANDA product - drospirenone and ethinyl estradiol tablets, 3 mg/0.02 mg. Defendants  
19 deny the remaining allegations in paragraph 65.

20 66. By filing ANDA No. 20-2594 under 21 U.S.C. § 355(j) for the purpose of obtaining  
21 approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of  
22 Mylan’s YAZ® ANDA product before the expiration of the ‘564 reissue patent, Mylan has  
23 committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and  
24 belief, the commercial manufacture, use, offer for sale, sale and/or importation of Mylan’s  
25 YAZ® ANDA product will also infringe one or more claims of the ‘564 reissue patent.

26           **ANSWER:** Denied.

27 67. Plaintiffs Bayer Schering and Bayer HealthCare are entitled to the relief provided by 35  
28 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval

1 relating to ANDA No. 20-2594 shall be a date which is not earlier than June 30, 2014, the  
2 current expiration date of the '564 reissue patent, or any later date of exclusivity to which Bayer  
3 becomes entitled. Bayer Schering and Bayer HealthCare are entitled to an award of damages and  
4 treble damages for any commercial sale or use of Mylan's YAZ® ANDA product, and any act  
5 committed by Mylan with respect to the subject matter claimed in the '564 reissue patent that is  
6 not within the limited exclusions of 35 U.S.C. § 271(e)(1).

7 **ANSWER:** Denied.

8 68. On information and belief, when Mylan filed ANDA No. 20-2594, it was aware of the  
9 '564 reissue patent and was aware that the filing of ANDA No. 20-2594 with the request for its  
10 approval prior to the expiration of the '564 reissue patent constituted an act of infringement of  
11 the '564 reissue patent.

12 **ANSWER:** Denied.

13 **GENERAL DENIAL**

14 Any allegation in Plaintiffs' Complaint not expressly admitted by Mylan is hereby  
15 denied. Having answered Plaintiffs' Complaint, Mylan denies that Plaintiffs are entitled to the  
16 relief requested in Plaintiffs' Prayer for Relief or to any relief whatsoever.

17 **SEPARATE DEFENSES**

18 Without prejudice to the denials set forth in its Answer to the Complaint, and without  
19 admitting any allegations of the Complaint not otherwise admitted, Mylan asserts the following  
20 separate defenses to the Complaint:

21 **FIRST SEPARATE DEFENSE**

22 The manufacture, use, or sale, offer for sale, or importation of the products that are the  
23 subject of ANDA No. 20-2594 have not infringed, do not infringe, and would not, if marketed,  
24 manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of  
25 the '564 reissue patent.

26 **SECOND SEPARATE DEFENSE**

27 The claims of the '564 reissue patent are invalid for failure to satisfy one or more of the  
28 conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.

**THIRD SEPARATE DEFENSE**

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent application leading to the '564 reissue patent, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the '564 reissue patent is infringed by the proposed product that is the subject of ANDA No. 20-2594.

**FOURTH SEPARATE DEFENSE**

Plaintiffs have failed to state a claim upon which relief can be granted.

**FIFTH SEPARATE DEFENSE**

Any and all additional defenses and counterclaims that discovery may reveal.

**COUNTERCLAIMS**

For their counterclaims against Plaintiffs/Counterclaim Defendants Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. ("Counterclaim Defendants"), Defendants/Counterclaim Plaintiffs Mylan Pharmaceuticals Inc. and Famy Care Ltd. (collectively "Counterclaim Plaintiffs") state as follows:

**PARTIES**

1. Upon information and belief, Bayer Schering Pharma AG purports and claims to be a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business in Müllerstrasse 178, 13353 Berlin, Germany.

2. Upon information and belief, Bayer HealthCare Pharmaceuticals Inc. purports and claims to be a corporation organized and existing under of the state of West Virginia, having a principal place of business at 6 West Belt, Wayne, New Jersey 07470.

3. Counterclaim Plaintiff Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") is a corporation organized under the laws of the State of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

4. Counterclaim Plaintiff Famy Care ("Famy Care") is a corporation organized under the laws of India with a place of business at 3rd Floor, Brady House, 12/14, Veer Nariman Road, Fort, Mumbai - 400 001, India.

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**JURISDICTION AND VENUE**

5. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. The Court has personal jurisdiction over Counterclaim Defendants because Counterclaim Defendants have availed themselves of the rights and privileges of this forum by suing Counterclaim Plaintiffs in this judicial District and, upon information and belief, because of Counterclaim Defendants' systematic and continuous contacts with Nevada by virtue of Counterclaim Defendants' distribution of drugs for sale and use in Nevada.

8. Venue for these Counterclaims is proper in this judicial District pursuant to 28 U.S.C. §§ 1391(b) and 1400(b).

**PATENTS IN SUIT**

9. On or about February 26, 2002, the United States Patent and Trademark Office ("USPTO") issued United States Reissue Patent No. 37,564 ("the '564 Patent"), titled "Composition for Concentration." Counterclaim Defendants are indicated in the records of the USPTO as the owners or assignees of the '564 Patent.

10. On information and belief, Counterclaim Defendants purport and claim to jointly own all rights, title and interest in and to the '564 Patent.

11. Upon information and belief, Bayer HealthCare Pharmaceuticals Inc. is indicated in the records of the United States Food and Drug Administration as the holder of New Drug Application No. 21-676 for YAZ<sup>®</sup> brand tablets which contain drospirenone and 17 $\alpha$ -ethinylestradiol, which are sold by Counterclaim Defendants.

12. The '564 Patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for YAZ<sup>®</sup>.

13. On or about October 29, 1996, the USPTO issued United States Patent No. 5,569,652 ("the '652 Patent"), titled "Dihydrospirorenone as an antiandrogen." Counterclaim Defendants are indicated in the records of the USPTO as the owners or assignees of the '652 Patent.

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1 14. On information and belief, Counterclaim Defendants purport and claim to jointly own all  
2 rights, title and interest in and to the '652 Patent.

3 15. The '652 Patent is listed in the Orange Book for YAZ<sup>®</sup>.

4 16. On or about August 25, 1998, the USPTO issued United States Patent No. 5,798,338  
5 ("the '338 Patent"), titled "Solid dosage forms that contain clathrates of 17 $\alpha$ -ethinyl estradiol."  
6 Counterclaim Defendants are indicated in the records of the USPTO as the owners or assignees  
7 of the '338 Patent.

8 17. On information and belief, Counterclaim Defendants purport and claim to jointly own all  
9 rights, title and interest in and to the '338 Patent.

10 18. The '338 Patent is listed in the Orange Book for YAZ<sup>®</sup>.

11 19. On or about September 7, 2004, the USPTO issued United States Patent No. 6,787,531  
12 ("the '531 Patent"), titled "Pharmaceutical composition for use as a contraceptive."  
13 Counterclaim Defendants are indicated in the records of the USPTO as the owners or assignees  
14 of the '338 Patent.

15 20. On information and belief, Counterclaim Defendants purport and claim to jointly own all  
16 rights, title and interest in and to the '531 Patent.

17 21. The '531 Patent is listed in the Orange Book for YAZ<sup>®</sup>.

18 22. On or about August 23, 2005, the USPTO issued United States Patent No. 6,933,395  
19 ("the '395 Patent"), titled "PROCESSING FOR PRODUCING OF DROSPIRENONE (6 $\beta$ , 7 $\beta$ ,  
20 15 $\beta$ , 16 $\beta$ -DIMETHYLENE-3-OXO-17 $\alpha$ -PREGN-4-EN-21, 17-CARBOLACTONE, DRSP) AS  
21 WELL AS 7 $\alpha$ -(3-HYDOXY-1-PROPLY)-6 $\beta$ , 7 $\beta$ ; 15 $\beta$ , 16 $\beta$ -DIMETHYLENE-5 $\beta$ -  
22 ANDROSTANE-3 $\beta$ , 5,17 $\beta$ -TRIOL(ZK 92836) AND 6 $\beta$ , 7 $\beta$ ; 15 $\beta$ , 16 $\beta$ -DIMETHYLENE-5 $\beta$ -  
23 HYDROXY." Counterclaim Defendants are indicated in the records of the USPTO as the  
24 owners or assignees of the '395 Patent.

25 23. On information and belief, Counterclaim Defendants purport and claim to jointly own all  
26 rights, title and interest in and to the '395 Patent.

27 24. The '395 Patent is listed in the Orange Book for YAZ<sup>®</sup>.

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25. On or about October 25, 2005, the USPTO issued United States Patent No. 6,958,326 (“the ’326 Patent”), titled “Cyclodextrin-drospirenone inclusion complexes.” Counterclaim Defendants are indicated in the records of the USPTO as the owners or assignees of the ’326 Patent.

26. On information and belief, Counterclaim Defendants purport and claim to jointly own all rights, title and interest in and to the ’326 Patent.

27. The ’326 Patent is listed in the Orange Book for YAZ<sup>®</sup>.

28. On or about January 16, 2007, the USPTO issued United States Patent No. 7,163,931 (“the ’931 Patent”), titled “Compositions of estrogen-cyclodextrin complexes.” Counterclaim Defendants are indicated in the records of the USPTO as the owners or assignees of the ’931 Patent.

29. On information and belief, Counterclaim Defendants purport and claim to jointly own all rights, title and interest in and to the ’931 Patent.

30. The ’931 Patent is listed in the Orange Book for YAZ<sup>®</sup>.

31. On or about September 16, 2003, the USPTO issued United States Reissue Patent No. 38,253 (“the ’253 Patent”), titled “Composition for contraception.” Counterclaim Defendants are indicated in the records of the USPTO as the owners or assignees of the ’253 Patent.

32. On information and belief, Counterclaim Defendants purport and claim to jointly own all rights, title and interest in and to the ’253 Patent.

33. The ’253 Patent is listed in the Orange Book for YAZ<sup>®</sup>.

34. On or about September 10, 2002, the USPTO issued United States Reissue Patent No. 37,838 (“the ’838 Patent”), titled “Composition for contraception.” Counterclaim Defendants are indicated in the records of the USPTO as the owners or assignees of the ’838 Patent.

35. On information and belief, Counterclaim Defendants purport and claim to jointly own all rights, title and interest in and to the ’838 Patent.

36. The ’838 Patent is listed in the Orange Book for YAZ<sup>®</sup>.

37. By letter dated March 7, 2011, McGuireWoods LLP, on behalf of Mylan Pharmaceuticals and Famy Care sent Counterclaim Defendants notice of the filing of its ANDA No. 20-2594,

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1 which included a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that the '564, '652, '338,  
2 '531, '395, '326, '931, '253, and '838 Patents are invalid, unenforceable, and/or will not be  
3 infringed by the manufacture, use, offer for sale, sale and/or importation of the product that is the  
4 subject of ANDA No. 20-2594.

5 38. On April 19, 2011, Counterclaim Defendants sued Counterclaim Plaintiffs alleging  
6 infringement of the '564 Patent but not the '652, '338, '531, '395, '326, '931, '253, or '838  
7 Patents.

8 **FIRST COUNT**

9 **(Declaratory Judgment of Invalidity of the '564 Patent)**

10 39. Counterclaim Plaintiffs restate and reallege each of the foregoing paragraphs as if fully  
11 set forth herein.

12 40. Counterclaim Defendants have accused Counterclaim Plaintiffs of infringing the '564  
13 Patent.

14 41. Counterclaim Plaintiffs deny infringement of the '564 Patent and allege that the '564  
15 Patent is invalid for failure to comply with one or more of the requirements for patentability set  
16 forth in Title 35 of the U.S. Patent Code, including 35 U.S.C. §§ 101, 102, 103, 112, and/or 116.

17 42. A definite and concrete, real and substantial, justiciable, and continuing case or  
18 controversy exists between Counterclaim Plaintiffs and Counterclaim Defendants regarding the  
19 infringement and validity of the '564 Patent that is of sufficient immediacy and reality to warrant  
20 the issuance of a Declaratory Judgment.

21 43. Counterclaim Plaintiffs are entitled to a judicial declaration that one or more of the claims  
22 of the '564 Patent are invalid.

23 **SECOND COUNT**

24 **(Declaratory Judgment of Non-Infringement of the '564 Patent)**

25 44. Counterclaim Plaintiffs restate and reallege each of the foregoing paragraphs as if fully  
26 set forth herein.

27 45. Counterclaim Defendants have accused Counterclaim Plaintiffs of infringing the '564  
28 Patent.

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1 46. Counterclaim Plaintiffs deny infringement of the '564 Patent and allege that the  
2 manufacture, use, sale, offer for sale, or importation of the products that are the subject of  
3 ANDA No. 20-2594 have not infringed, do not infringe, and would not, if manufactured, used,  
4 sold, offered for sale, or imported, infringe any valid or enforceable claim of the '564 Patent.

5 47. A definite and concrete, real and substantial, justiciable, and continuing case or  
6 controversy exists between Counterclaim Plaintiffs and Counterclaim Defendants regarding the  
7 infringement and validity of the '564 Patent that is of sufficient immediacy and reality to warrant  
8 the issuance of a Declaratory Judgment.

9 48. Counterclaim Plaintiffs are entitled to a judicial declaration that the manufacture, use,  
10 sale, offer for sale, or importation of the products that are the subject of ANDA No. 20-2594  
11 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale,  
12 or imported, infringe any valid or enforceable claim of the '564 Patent.

### 13 **THIRD COUNT**

#### 14 **(Declaratory Judgment of Non-Infringement of the '652 Patent)**

15 49. Counterclaim Plaintiffs restate and reallege each of the foregoing paragraphs as if fully  
16 set forth herein.

17 50. Counterclaim Defendants have alleged that the filing of ANDA No. 20-2594 constitutes  
18 infringement of at least one Orange Book listed patent, but have not alleged infringement of the  
19 '652 patent.

20 51. Notwithstanding the fact that Counterclaim Defendants have not yet brought an action for  
21 patent infringement, Counterclaim Defendants are not precluded from individually and/or  
22 collectively bringing an action for patent infringement at a later time.

23 52. Counterclaim Defendants' conduct has created an uncertainty of legal rights with respect  
24 to the '652 patent and ANDA No. 20-2594.

25 53. Counterclaim Plaintiffs deny infringement of the '652 Patent and allege that the  
26 manufacture, use, sale, offer for sale, or importation of the products that are the subject of  
27 ANDA No. 20-2594 have not infringed, do not infringe, and would not, if manufactured, used,  
28 sold, offered for sale, or imported, infringe any valid or enforceable claim of the '652 Patent.

1 54. A definite and concrete, real and substantial, justiciable, and continuing case or  
2 controversy exists between Counterclaim Plaintiffs and Counterclaim Defendants regarding the  
3 infringement and validity of the '652 Patent that is of sufficient immediacy and reality to warrant  
4 the issuance of a Declaratory Judgment.

5 55. Counterclaim Plaintiffs are entitled to a judicial declaration that the manufacture, use,  
6 sale, offer for sale, or importation of the products that are the subject of ANDA No. 20-2594  
7 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale,  
8 or imported, infringe any valid or enforceable claim of the '652 Patent.

9 **FOURTH COUNT**

10 **(Declaratory Judgment of Non-Infringement of the '338 Patent)**

11 56. Counterclaim Plaintiffs restate and reallege each of the foregoing paragraphs as if fully  
12 set forth herein.

13 57. Counterclaim Defendants have alleged that the filing of ANDA No. 20-2594 constitutes  
14 infringement of at least one Orange Book listed patent, but have not alleged infringement of the  
15 '338 patent.

16 58. Notwithstanding the fact that Counterclaim Defendants have not yet brought an action for  
17 patent infringement, Counterclaim Defendants are not precluded from individually and/or  
18 collectively bringing an action for patent infringement at a later time.

19 59. Counterclaim Defendants' conduct has created an uncertainty of legal rights with respect  
20 to the '338 patent and ANDA No. 20-2594.

21 60. Counterclaim Plaintiffs deny infringement of the '338 Patent and allege that the  
22 manufacture, use, sale, offer for sale, or importation of the products that are the subject of  
23 ANDA No. 20-2594 have not infringed, do not infringe, and would not, if manufactured, used,  
24 sold, offered for sale, or imported, infringe any valid or enforceable claim of the '338 Patent.

25 61. A definite and concrete, real and substantial, justiciable, and continuing case or  
26 controversy exists between Counterclaim Plaintiffs and Counterclaim Defendants regarding the  
27 infringement and validity of the '338 Patent that is of sufficient immediacy and reality to warrant  
28 the issuance of a Declaratory Judgment.

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62. Counterclaim Plaintiffs are entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of ANDA No. 20-2594 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '338 Patent.

**FIFTH COUNT**

**(Declaratory Judgment of Invalidity of the '531 Patent)**

63. Counterclaim Plaintiffs restate and reallege each of the foregoing paragraphs as if fully set forth herein.

64. Counterclaim Defendants have alleged that the filing of ANDA No. 20-2594 constitutes infringement of at least one Orange Book listed patent, but have not alleged infringement of the '531 patent.

65. Notwithstanding the fact that Counterclaim Defendants have not yet brought an action for patent infringement, Counterclaim Defendants are not precluded from individually and/or collectively bringing an action for patent infringement at a later time.

66. Counterclaim Defendants' conduct has created an uncertainty of legal rights with respect to the '531 patent and ANDA No. 20-2594.

67. Counterclaim Plaintiffs deny infringement of the '531 Patent and allege that the '531 Patent is invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Patent Code, including 35 U.S.C. §§ 101, 102, 103, 112, and/or 116.

68. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Counterclaim Plaintiffs and Counterclaim Defendants regarding the infringement and validity of the '531 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

69. Counterclaim Plaintiffs are entitled to a judicial declaration that one or more of the claims of the '531 Patent are invalid.

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**SIXTH COUNT**

**(Declaratory Judgment of Invalidity of the '395 Patent)**

70. Counterclaim Plaintiffs restate and reallege each of the foregoing paragraphs as if fully set forth herein.

71. Counterclaim Defendants have alleged that the filing of ANDA No. 20-2594 constitutes infringement of at least one Orange Book listed patent, but have not alleged infringement of the '395 patent.

72. Notwithstanding the fact that Counterclaim Defendants have not yet brought an action for patent infringement, Counterclaim Defendants are not precluded from individually and/or collectively bringing an action for patent infringement at a later time.

73. Counterclaim Defendants' conduct has created an uncertainty of legal rights with respect to the '395 patent and ANDA No. 20-2594.

74. Counterclaim Plaintiffs deny infringement of the '395 Patent and allege that the '395 Patent is invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Patent Code, including 35 U.S.C. §§ 101, 102, 103, 112, and/or 116.

75. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Counterclaim Plaintiffs and Counterclaim Defendants regarding the infringement and validity of the '395 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

76. Counterclaim Plaintiffs are entitled to a judicial declaration that one or more of the claims of the '395 Patent are invalid.

**SEVENTH COUNT**

**(Declaratory Judgment of Non-Infringement of the '326 Patent)**

77. Counterclaim Plaintiffs restate and reallege each of the foregoing paragraphs as if fully set forth herein.

78. Counterclaim Defendants have alleged that the filing of ANDA No. 20-2594 constitutes infringement of at least one Orange Book listed patent, but have not alleged infringement of the '326 patent.

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1 79. Notwithstanding the fact that Counterclaim Defendants have not yet brought an action for  
2 patent infringement, Counterclaim Defendants are not precluded from individually and/or  
3 collectively bringing an action for patent infringement at a later time.

4 80. Counterclaim Defendants' conduct has created an uncertainty of legal rights with respect  
5 to the '326 patent and ANDA No. 20-2594.

6 81. Counterclaim Plaintiffs deny infringement of the '326 Patent and allege that the  
7 manufacture, use, sale, offer for sale, or importation of the products that are the subject of  
8 ANDA No. 20-2594 have not infringed, do not infringe, and would not, if manufactured, used,  
9 sold, offered for sale, or imported, infringe any valid or enforceable claim of the '326 Patent.

10 82. A definite and concrete, real and substantial, justiciable, and continuing case or  
11 controversy exists between Counterclaim Plaintiffs and Counterclaim Defendants regarding the  
12 infringement and validity of the '326 Patent that is of sufficient immediacy and reality to warrant  
13 the issuance of a Declaratory Judgment.

14 83. Counterclaim Plaintiffs are entitled to a judicial declaration that the manufacture, use,  
15 sale, offer for sale, or importation of the products that are the subject of ANDA No. 20-2594  
16 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale,  
17 or imported, infringe any valid or enforceable claim of the '326 Patent.

#### 18 **EIGHTH COUNT**

##### 19 **(Declaratory Judgment of Non-Infringement of the '931 Patent)**

20 84. Counterclaim Plaintiffs restate and reallege each of the foregoing paragraphs as if fully  
21 set forth herein.

22 85. Counterclaim Defendants have alleged that the filing of ANDA No. 20-2594 constitutes  
23 infringement of at least one Orange Book listed patent, but have not alleged infringement of the  
24 '931 patent.

25 86. Notwithstanding the fact that Counterclaim Defendants have not yet brought an action for  
26 patent infringement, Counterclaim Defendants are not precluded from individually and/or  
27 collectively bringing an action for patent infringement at a later time.

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87. Counterclaim Defendants' conduct has created an uncertainty of legal rights with respect to the '931 patent and ANDA No. 20-2594.

88. Counterclaim Plaintiffs deny infringement of the '931 Patent and allege that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of ANDA No. 20-2594 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '931 Patent.

89. A definite and concrete, real and substantial, justiciable, and continuing case or controversy exists between Counterclaim Plaintiffs and Counterclaim Defendants regarding the infringement and validity of the '931 Patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

90. Counterclaim Plaintiffs are entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the products that are the subject of ANDA No. 20-2594 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale, or imported, infringe any valid or enforceable claim of the '931 Patent.

### **NINTH COUNT**

#### **(Declaratory Judgment of Invalidity of the '253 Patent)**

91. Counterclaim Plaintiffs restate and reallege each of the foregoing paragraphs as if fully set forth herein.

92. Counterclaim Defendants have alleged that the filing of ANDA No. 20-2594 constitutes infringement of at least one Orange Book listed patent, but have not alleged infringement of the '253 patent.

93. Notwithstanding the fact that Counterclaim Defendants have not yet brought an action for patent infringement, Counterclaim Defendants are not precluded from individually and/or collectively bringing an action for patent infringement at a later time.

94. Counterclaim Defendants' conduct has created an uncertainty of legal rights with respect to the '253 patent and ANDA No. 20-2594.

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1 95. Counterclaim Plaintiffs deny infringement of the '253 Patent and allege that the '253  
2 Patent is invalid for failure to comply with one or more of the requirements for patentability set  
3 forth in Title 35 of the U.S. Patent Code, including 35 U.S.C. §§ 101, 102, 103, 112, and/or 116.

4 96. A definite and concrete, real and substantial, justiciable, and continuing case or  
5 controversy exists between Counterclaim Plaintiffs and Counterclaim Defendants regarding the  
6 infringement and validity of the '253 Patent that is of sufficient immediacy and reality to warrant  
7 the issuance of a Declaratory Judgment.

8 97. Counterclaim Plaintiffs are entitled to a judicial declaration that one or more of the claims  
9 of the '253 Patent are invalid.

10 **TENTH COUNT**

11 **(Declaratory Judgment of Non-Infringement of the '838 Patent)**

12 98. Counterclaim Plaintiffs restate and reallege each of the foregoing paragraphs as if fully  
13 set forth herein.

14 99. Counterclaim Defendants have alleged that the filing of ANDA No. 20-2594 constitutes  
15 infringement of at least one Orange Book listed patent, but have not alleged infringement of the  
16 '838 patent.

17 100. Notwithstanding the fact that Counterclaim Defendants have not yet brought an action for  
18 patent infringement, Counterclaim Defendants are not precluded from individually and/or  
19 collectively bringing an action for patent infringement at a later time.

20 101. Counterclaim Defendants' conduct has created an uncertainty of legal rights with respect  
21 to the '838 patent and ANDA No. 20-2594.

22 102. Counterclaim Plaintiffs deny infringement of the '838 Patent and allege that the  
23 manufacture, use, sale, offer for sale, or importation of the products that are the subject of  
24 ANDA No. 20-2594 have not infringed, do not infringe, and would not, if manufactured, used,  
25 sold, offered for sale, or imported, infringe any valid or enforceable claim of the '838 Patent.

26 103. A definite and concrete, real and substantial, justiciable, and continuing case or  
27 controversy exists between Counterclaim Plaintiffs and Counterclaim Defendants regarding the  
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1 infringement and validity of the '838 Patent that is of sufficient immediacy and reality to warrant  
2 the issuance of a Declaratory Judgment.

3 104. Counterclaim Plaintiffs are entitled to a judicial declaration that the manufacture, use,  
4 sale, offer for sale, or importation of the products that are the subject of ANDA No. 20-2594  
5 have not infringed, do not infringe, and would not, if manufactured, used, sold, offered for sale,  
6 or imported, infringe any valid or enforceable claim of the '838 Patent.

7 **ELEVENTH COUNT**

8 **(Declaratory Judgment of Invalidity of the '838 Patent)**

9 105. Counterclaim Plaintiffs restate and reallege each of the foregoing paragraphs as if fully  
10 set forth herein.

11 106. Counterclaim Defendants have alleged that the filing of ANDA No. 20-2594 constitutes  
12 infringement of at least one Orange Book listed patent, but have not alleged infringement of the  
13 '838 patent.

14 107. Notwithstanding the fact that Counterclaim Defendants have not yet brought an action for  
15 patent infringement, Counterclaim Defendants are not precluded from individually and/or  
16 collectively bringing an action for patent infringement at a later time.

17 108. Counterclaim Defendants' conduct has created an uncertainty of legal rights with respect  
18 to the '838 patent and ANDA No. 20-2594.

19 109. Counterclaim Plaintiffs deny infringement of the '838 Patent and allege that the '838  
20 Patent is invalid for failure to comply with one or more of the requirements for patentability set  
21 forth in Title 35 of the U.S. Patent Code, including 35 U.S.C. §§ 101, 102, 103, 112, and/or 116.

22 110. A definite and concrete, real and substantial, justiciable, and continuing case or  
23 controversy exists between Counterclaim Plaintiffs and Counterclaim Defendants regarding the  
24 infringement and validity of the '838 Patent that is of sufficient immediacy and reality to warrant  
25 the issuance of a Declaratory Judgment.

26 111. Counterclaim Plaintiffs are entitled to a judicial declaration that one or more of the claims  
27 of the '838 Patent are invalid.

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**PRAYER FOR RELIEF**

WHEREFORE, Defendants/Counterclaim Plaintiffs respectfully pray for judgment in their favor and against Plaintiffs/Counterclaim Defendants:

(a) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and would not infringe any valid or enforceable claim of the '564 Patent, either literally or under the doctrine of equivalents;

(b) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and would not induce the infringement of any valid or enforceable claim of the '564 Patent;

(c) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and would not contributorily infringe any valid or enforceable claim of the '564 Patent;

(d) Declaring that the claims of the '564 Patent are invalid;

(e) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and would not infringe any valid or enforceable claim of the '652 Patent, either literally or under the doctrine of equivalents;

(f) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and would not induce the infringement of any valid or enforceable claim of the '652 Patent;

(g) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and would not contributorily infringe any valid or enforceable claim of the '652 Patent;

(h) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and would not infringe any valid or enforceable claim of the '338 Patent, either literally or under the doctrine of equivalents;

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(i) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and would not induce the infringement of any valid or enforceable claim of the '338 Patent;

(j) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and would not contributorily infringe any valid or enforceable claim of the '338 Patent;

(k) Declaring that the claims of the '531 Patent are invalid;

(l) Declaring that the claims of the '395 Patent are invalid;

(m) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and would not infringe any valid or enforceable claim of the '326 Patent, either literally or under the doctrine of equivalents;

(n) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and would not induce the infringement of any valid or enforceable claim of the '326 Patent;

(o) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and would not contributorily infringe any valid or enforceable claim of the '326 Patent;

(p) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and would not infringe any valid or enforceable claim of the '931 Patent, either literally or under the doctrine of equivalents;

(q) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and would not induce the infringement of any valid or enforceable claim of the '931 Patent;

(r) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and would not contributorily infringe any valid or enforceable claim of the '931 Patent;



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- 1 (s) Declaring that the claims of the '253 Patent are invalid;
- 2 (t) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug
- 3 products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and
- 4 would not infringe any valid or enforceable claim of the '838 Patent, either literally or under the
- 5 doctrine of equivalents;
- 6 (u) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug
- 7 products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and
- 8 would not induce the infringement of any valid or enforceable claim of the '838 Patent;
- 9 (v) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug
- 10 products that are the subject of ANDA No. 20-2594 has not infringed, does not infringe and
- 11 would not contributorily infringe any valid or enforceable claim of the '838 Patent;
- 12 (w) Declaring that the claims of the '838 Patent are invalid;
- 13 (x) Ordering that Plaintiff/Counterclaim Defendants' Complaint be dismissed with
- 14 prejudice and judgment entered in favor of Defendants/Counterclaim Plaintiffs;
- 15 (y) Declaring this case exceptional and awarding Defendants/Counterclaim Plaintiffs
- 16 reasonable attorney fees and costs of these Counterclaims pursuant to 35 U.S.C. §285; and
- 17 (z) Awarding Defendants/Counterclaim Plaintiffs such other and further relief as the
- 18 Court may deem just and proper.

19 DATED this 15th day of August, 2011.

20

21 /s/ Patrick J. Reilly

22 Patrick J. Reilly, Esq.

23 Holland & Hart LLP

24 9555 Hillwood Drive, Second Floor

25 Las Vegas, Nevada 89134

26 *Attorneys for Defendants*

27

28

**CERTIFICATE OF SERVICE**

I hereby certify that on the 15th day of August, 2011, a true and correct copy of the foregoing **ANSWER, DEFENSES AND COUNTERCLAIMS OF MYLAN PHARMACEUTICALS INC., MYLAN INC. AND FAMY CARE LTD.** was served on counsel through the Court's electronic service system as follows:

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